

FIGURE 1

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Once-Weekly Eprex® alpha Increases Hemoglobin and Decreases Ribavirin Dose Reductions Among HCV-Infected Patients Who Develop Anemia on Ribavirin/Interferon alpha-2b Therapy

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ABSTRACT

Background: Anemia is a major side effect of ribavirin (RBV) therapy. Eprex® (epoetin alfa) is a recombinant human erythropoietin (EPO) that stimulates red blood cell production. We evaluated the effect of Eprex on hemoglobin (Hb) levels and RBV dose reductions in HCV-infected patients receiving RBV/interferon (IFN) therapy.

Methods: A total of 100 HCV-infected patients were enrolled in a randomized, controlled trial. The patients were randomized to receive either Eprex or placebo (PBO) in addition to RBV/IFN therapy. The primary endpoint was the change in Hb levels from baseline to week 12.

Results: At baseline, the mean Hb level was 11.5 g/dL. By week 12, the mean Hb level had increased to 12.5 g/dL in the Eprex group and to 11.8 g/dL in the PBO group. The difference between the two groups was statistically significant (p < 0.05).

Conclusions: The addition of Eprex to RBV/IFN therapy significantly increased Hb levels and decreased the need for RBV dose reductions. This suggests that Eprex may be a useful adjunctive therapy for HCV-infected patients with anemia.

INTRODUCTION

Chronic hepatitis C virus (HCV) infection is a leading cause of liver disease. The standard of care for HCV infection is a combination of RBV and IFN. However, RBV therapy is often limited by side effects, particularly anemia.

Anemia is a common side effect of RBV therapy, occurring in up to 50% of patients. It is caused by a combination of direct bone marrow toxicity and decreased erythropoietin production.

The use of Eprex, a recombinant human EPO, has been shown to increase Hb levels and reduce the need for RBV dose reductions in HCV-infected patients.

In this study, we evaluated the effect of Eprex on Hb levels and RBV dose reductions in a larger group of HCV-infected patients.

STUDY OBJECTIVES

The primary objective of this study was to determine the effect of Eprex on Hb levels and RBV dose reductions in HCV-infected patients. Secondary objectives included evaluating the effect of Eprex on quality of life and healthcare costs.

The study was a randomized, controlled trial. Patients were randomized to receive either Eprex or placebo in addition to RBV/IFN therapy. The study was conducted over a 12-week period.

The primary endpoint was the change in Hb levels from baseline to week 12. Secondary endpoints included the number of RBV dose reductions and the number of patients who completed the study.

The study was approved by the Institutional Review Boards at all participating sites. All patients gave informed consent before enrollment.

RESULTS

At baseline, the mean Hb level was 11.5 g/dL. By week 12, the mean Hb level had increased to 12.5 g/dL in the Eprex group and to 11.8 g/dL in the PBO group. The difference between the two groups was statistically significant (p < 0.05).

The number of RBV dose reductions was significantly lower in the Eprex group compared to the PBO group (p < 0.05). This suggests that Eprex may help maintain Hb levels and reduce the need for RBV dose reductions.

The number of patients who completed the study was also significantly higher in the Eprex group compared to the PBO group (p < 0.05).

There were no significant differences between the two groups in terms of quality of life or healthcare costs.

CONCLUSIONS

The addition of Eprex to RBV/IFN therapy significantly increased Hb levels and decreased the need for RBV dose reductions. This suggests that Eprex may be a useful adjunctive therapy for HCV-infected patients with anemia.

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DISCUSSION

The results of this study suggest that Eprex may be a useful adjunctive therapy for HCV-infected patients with anemia. The addition of Eprex to RBV/IFN therapy significantly increased Hb levels and decreased the need for RBV dose reductions.

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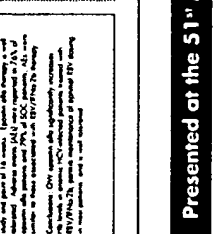
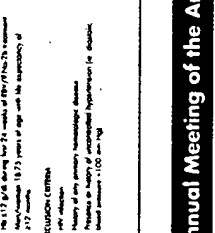
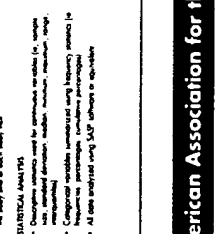
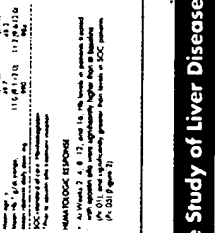
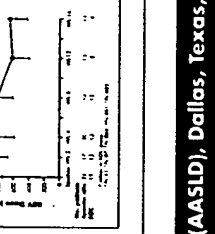
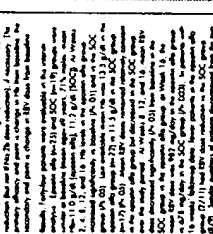
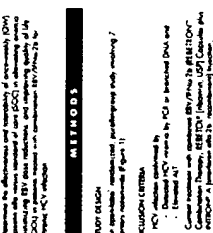
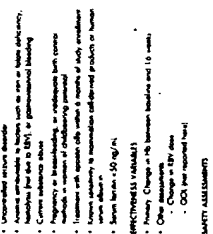
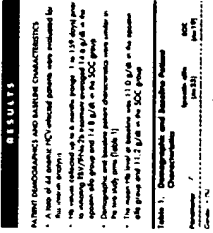
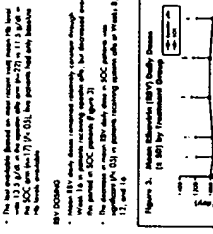
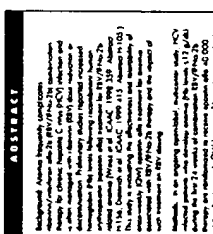
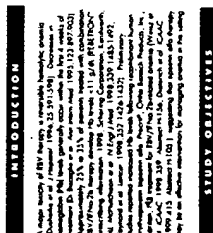
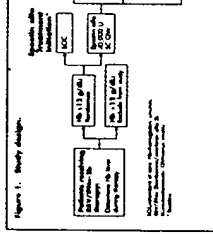
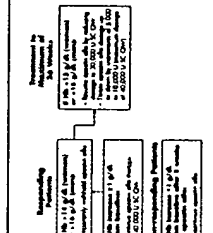
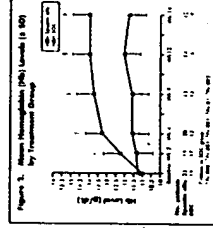
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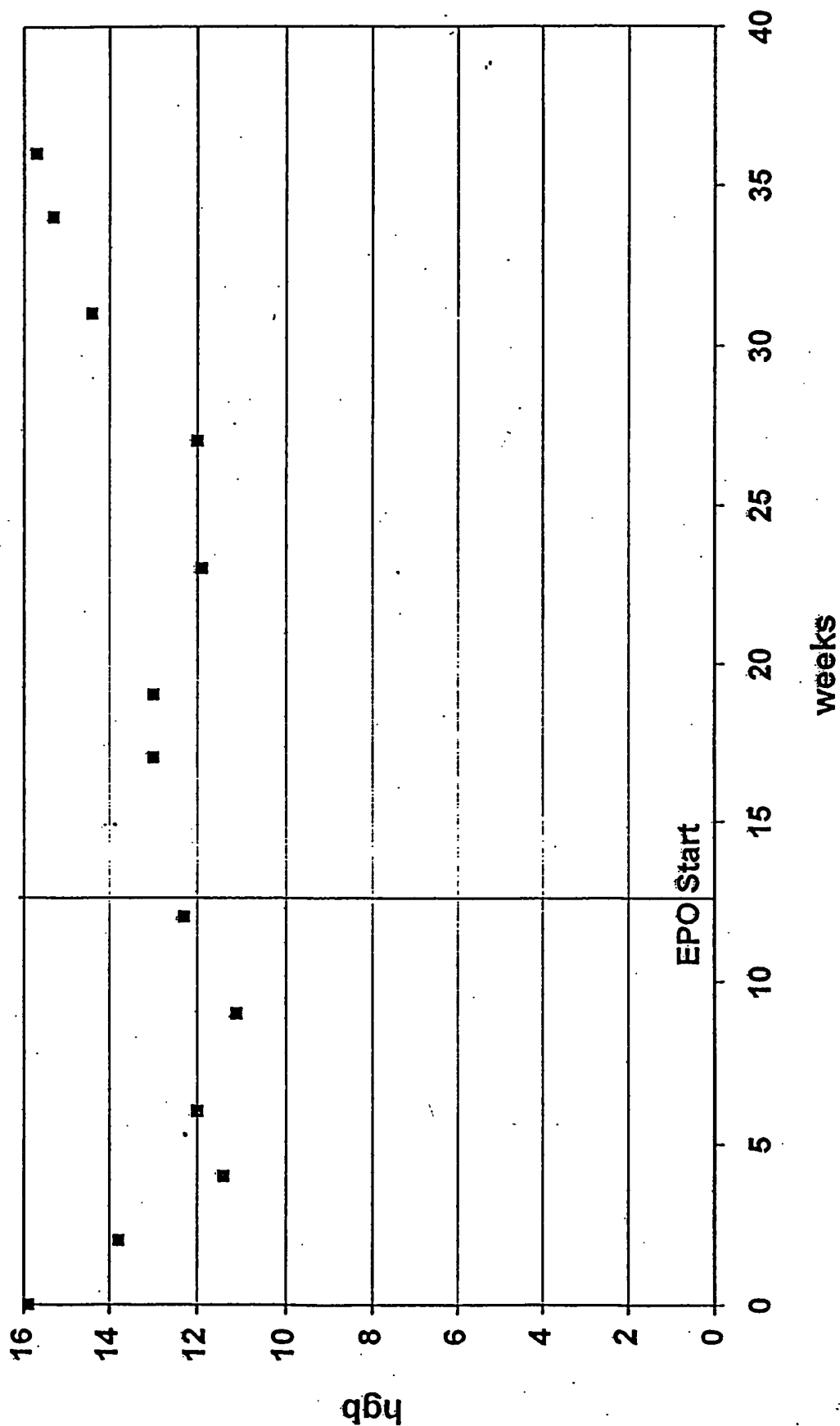
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2. Brou N, Westerman R, Hossain T, et al. Once-weekly Eprex alpha increases hemoglobin and decreases ribavirin dose reductions among HCV-infected patients who develop anemia on ribavirin/interferon alpha-2b therapy. *Ann Intern Med*. 2000;132:829-834.
3. Hossain T, Westerman R, Brou N, et al. Once-weekly Eprex alpha increases hemoglobin and decreases ribavirin dose reductions among HCV-infected patients who develop anemia on ribavirin/interferon alpha-2b therapy. *Ann Intern Med*. 2000;132:829-834.
4. Bini E, Sulkowski M, Dieterich D, et al. Once-weekly Eprex alpha increases hemoglobin and decreases ribavirin dose reductions among HCV-infected patients who develop anemia on ribavirin/interferon alpha-2b therapy. *Ann Intern Med*. 2000;132:829-834.



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Figure 2.1

Subject #2



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Subject #3

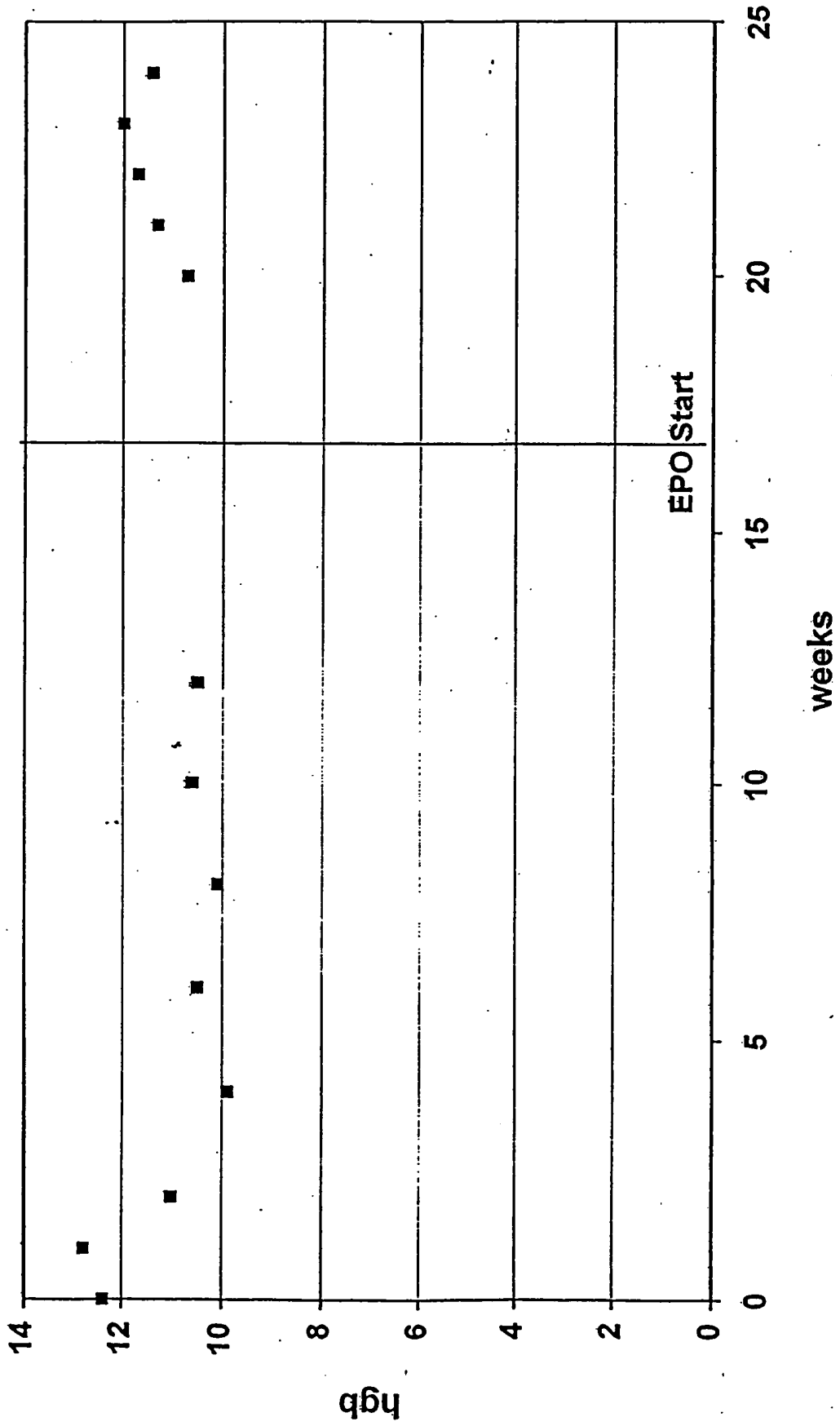


FIGURE 2.2

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FIGURE 3

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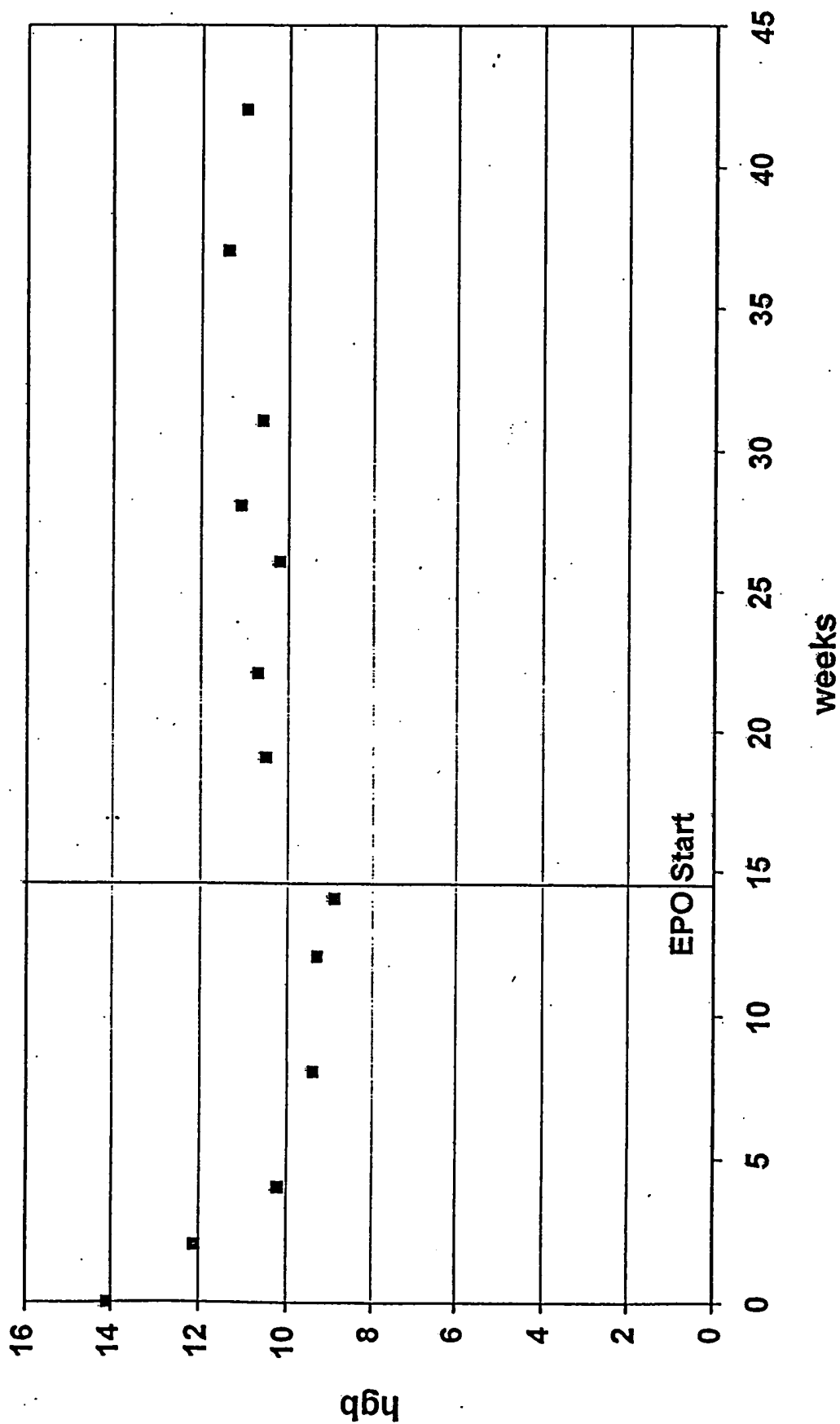
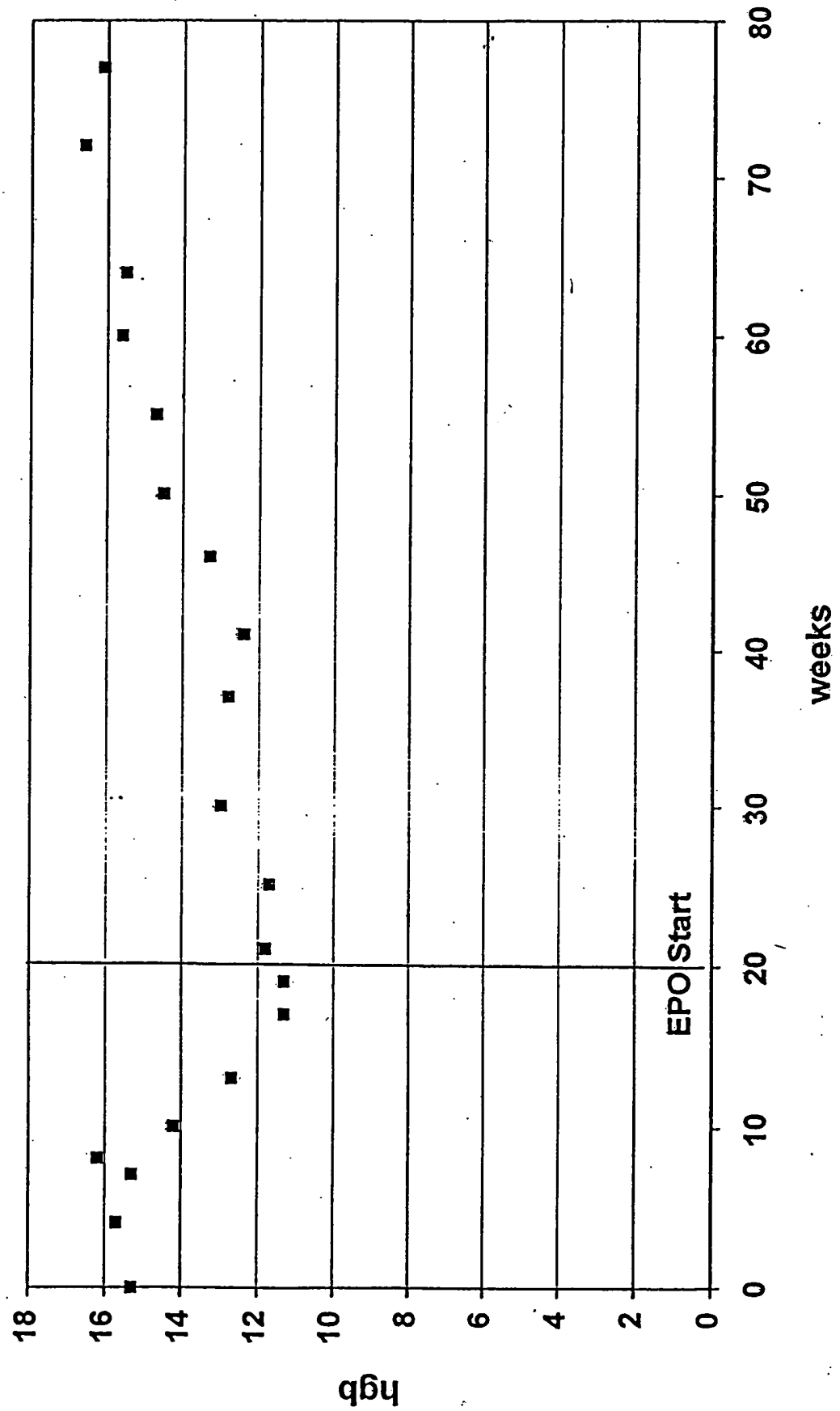


FIGURE 2.4

Subject #5



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Subject #6

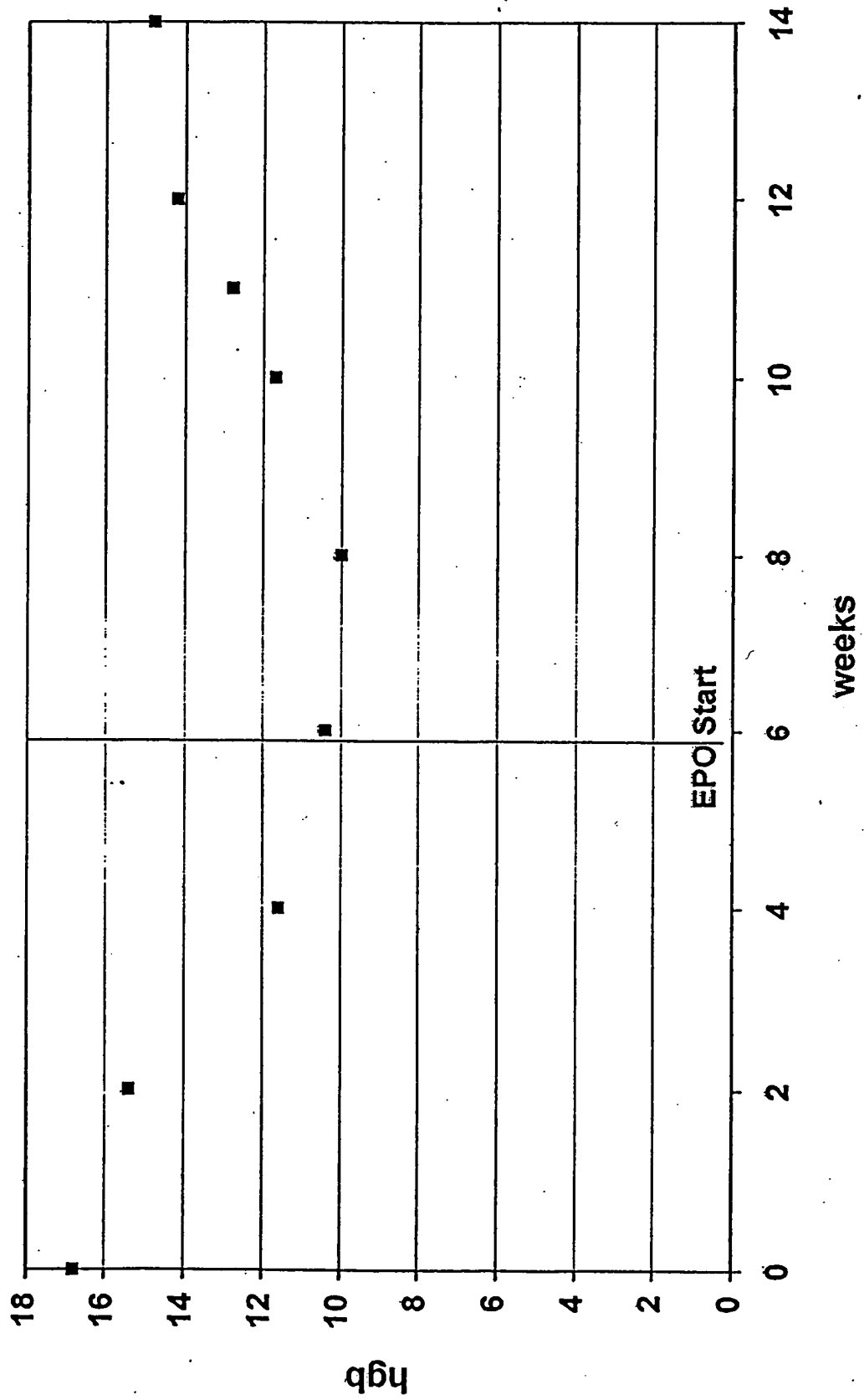
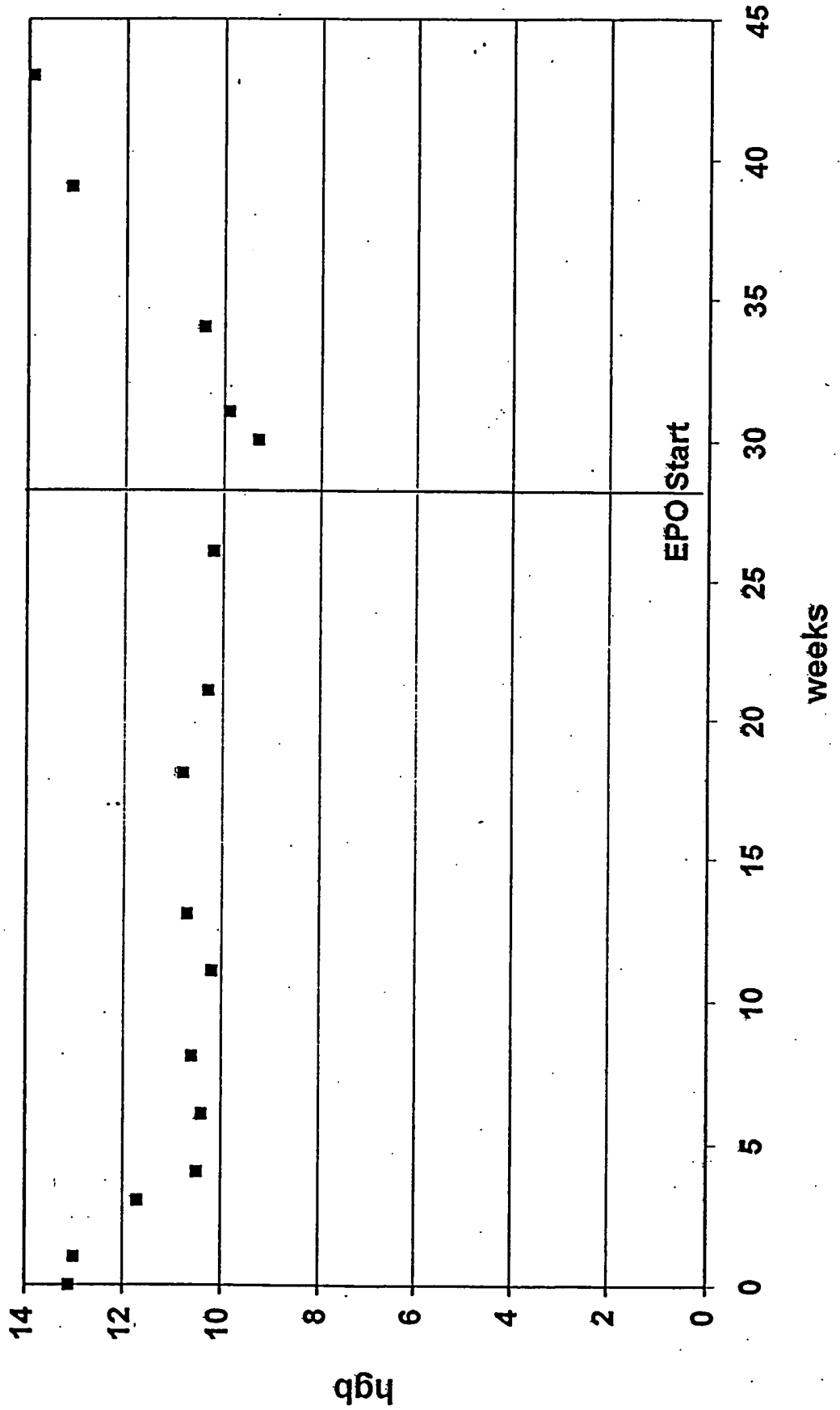


FIGURE 2.5

Subject #7

FIGURE 2.6



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Subject #8

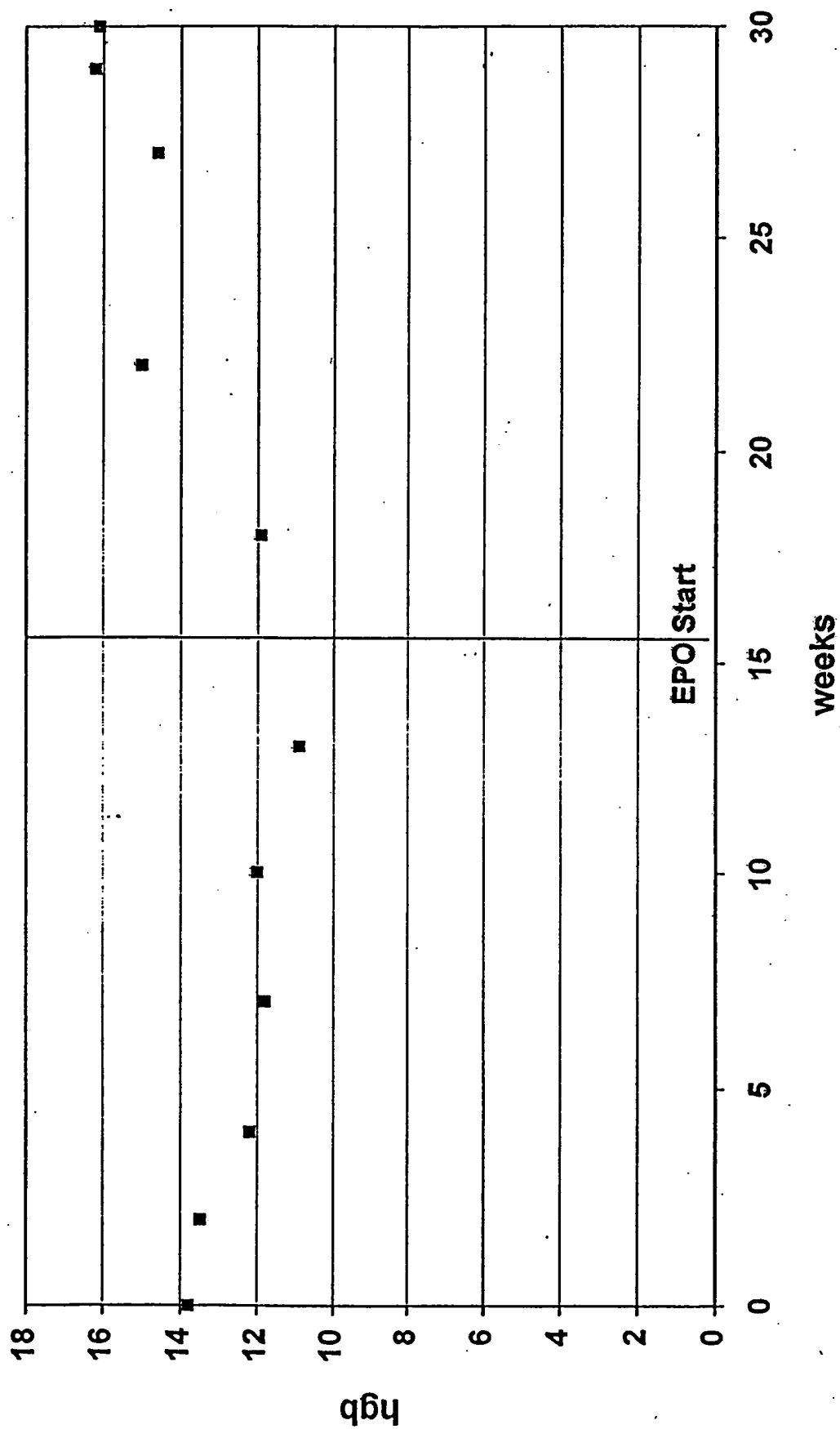


FIGURE 2.7

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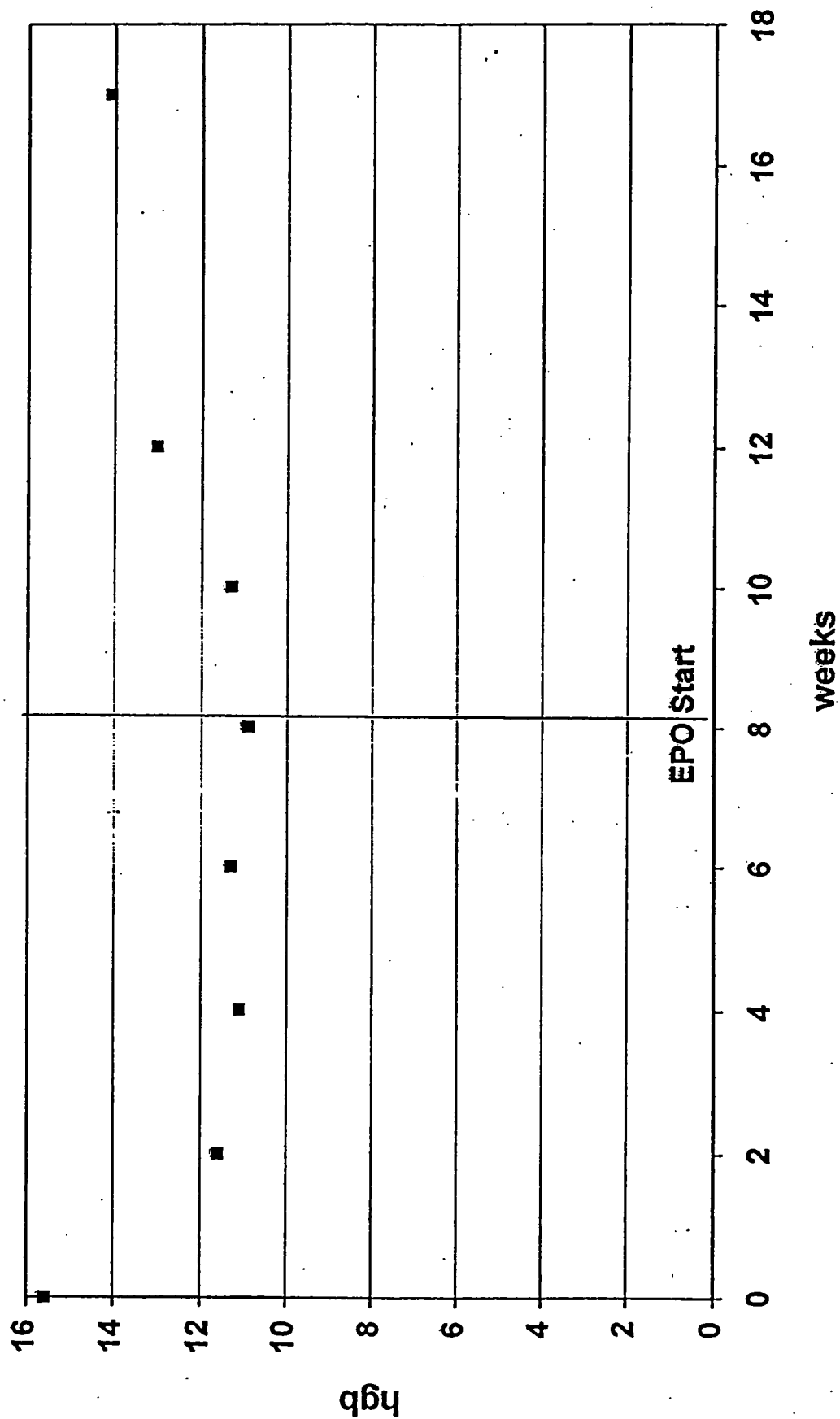
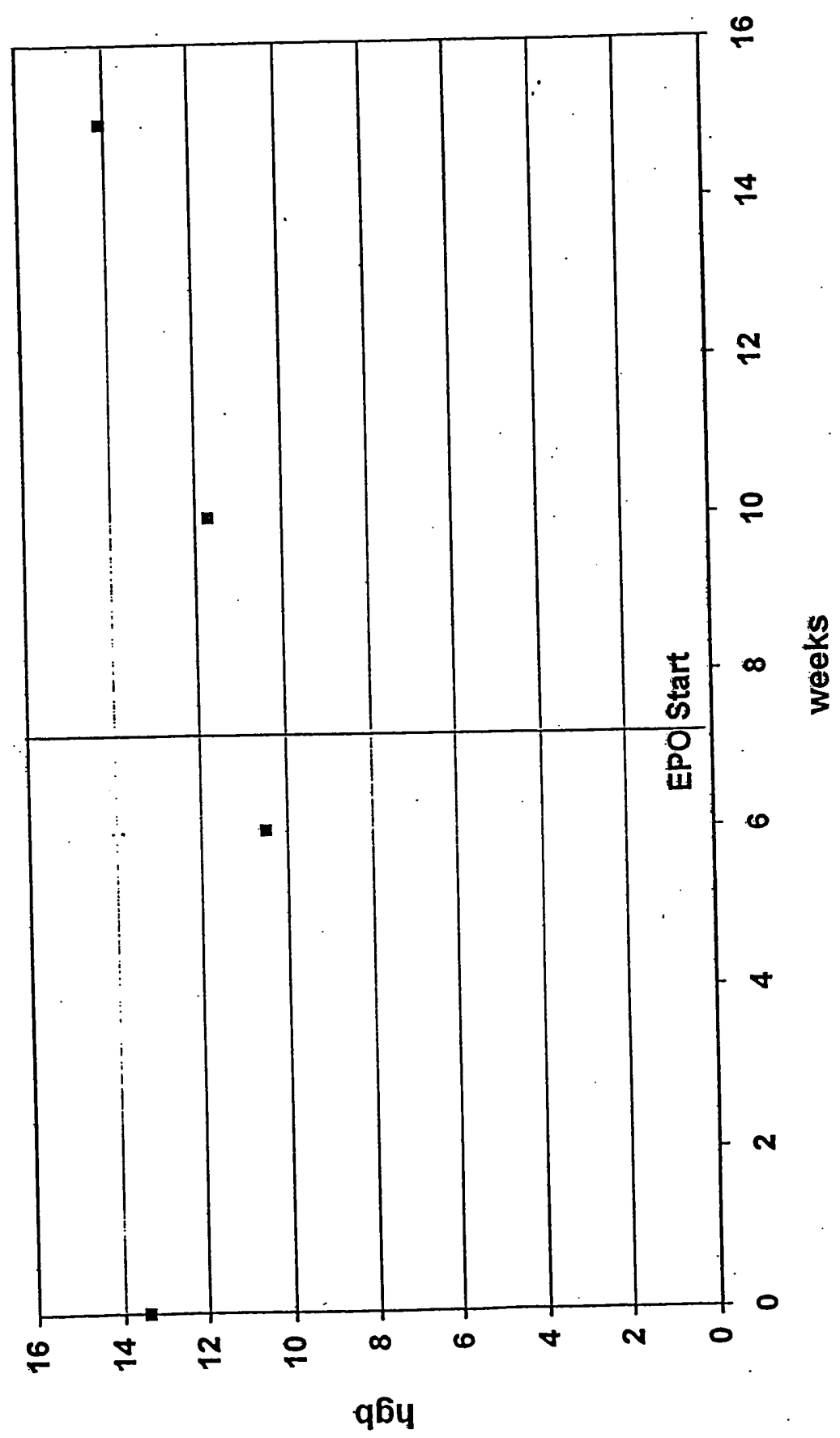


FIGURE 2.8

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FIGURE 9



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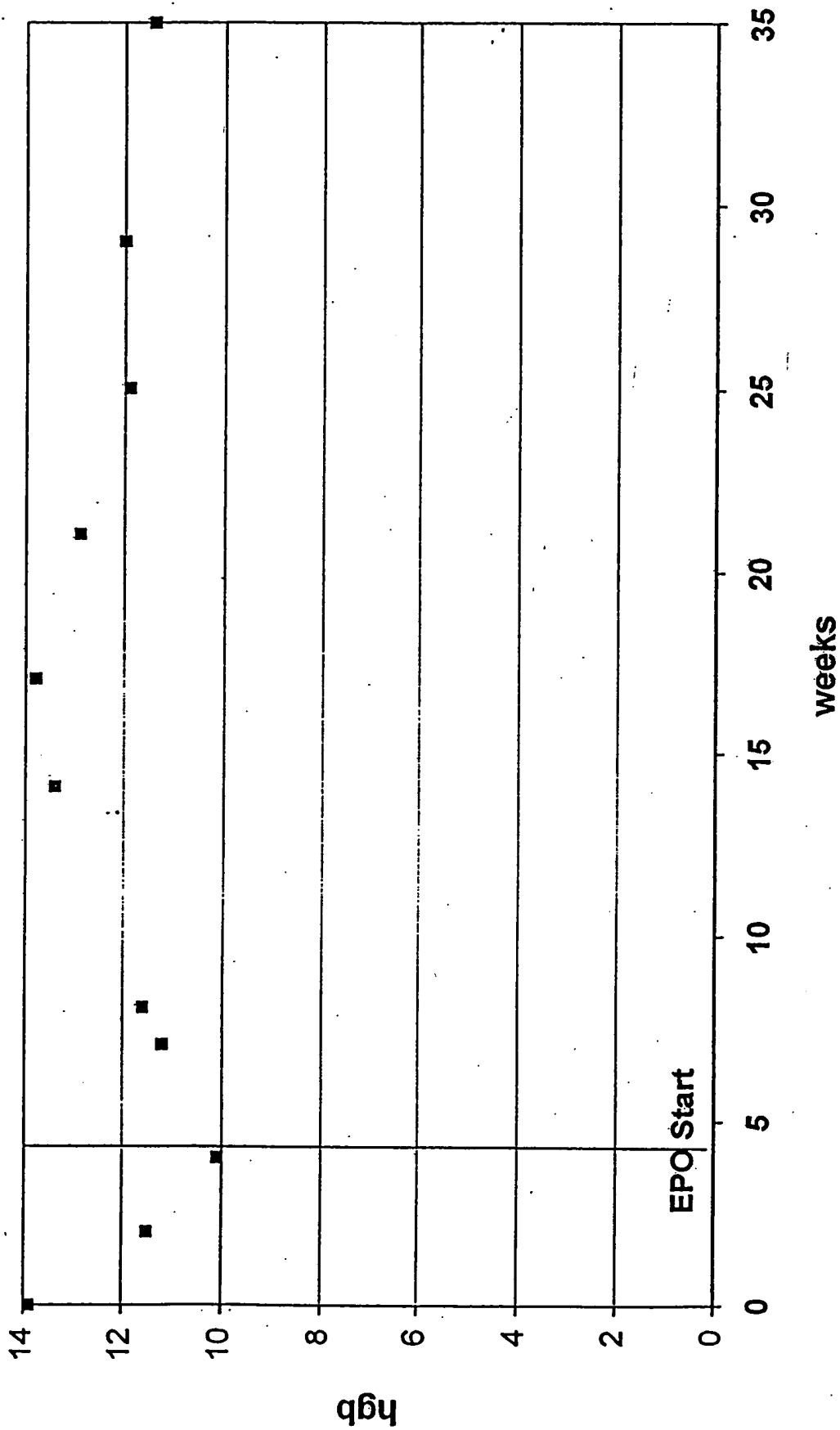
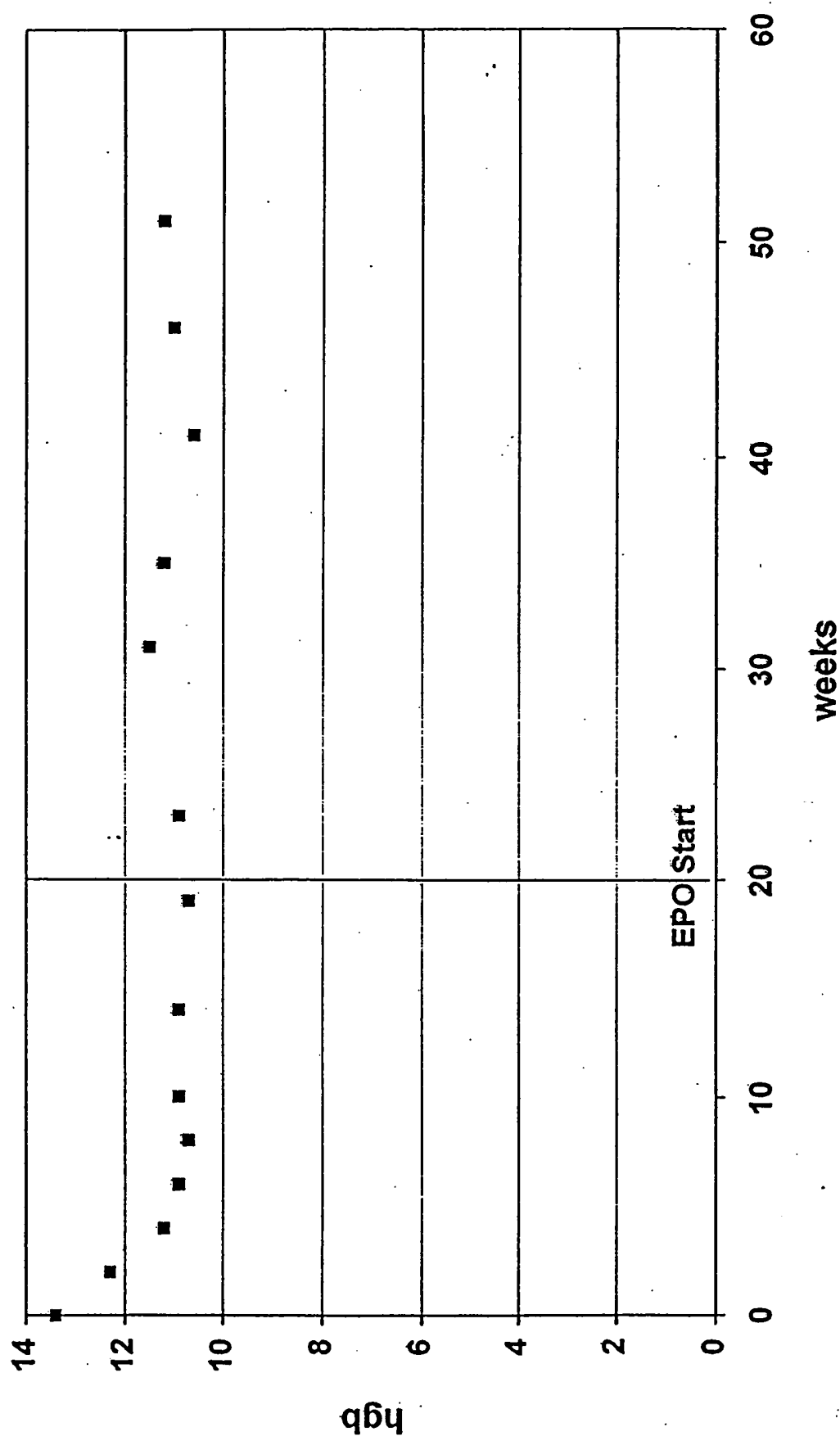


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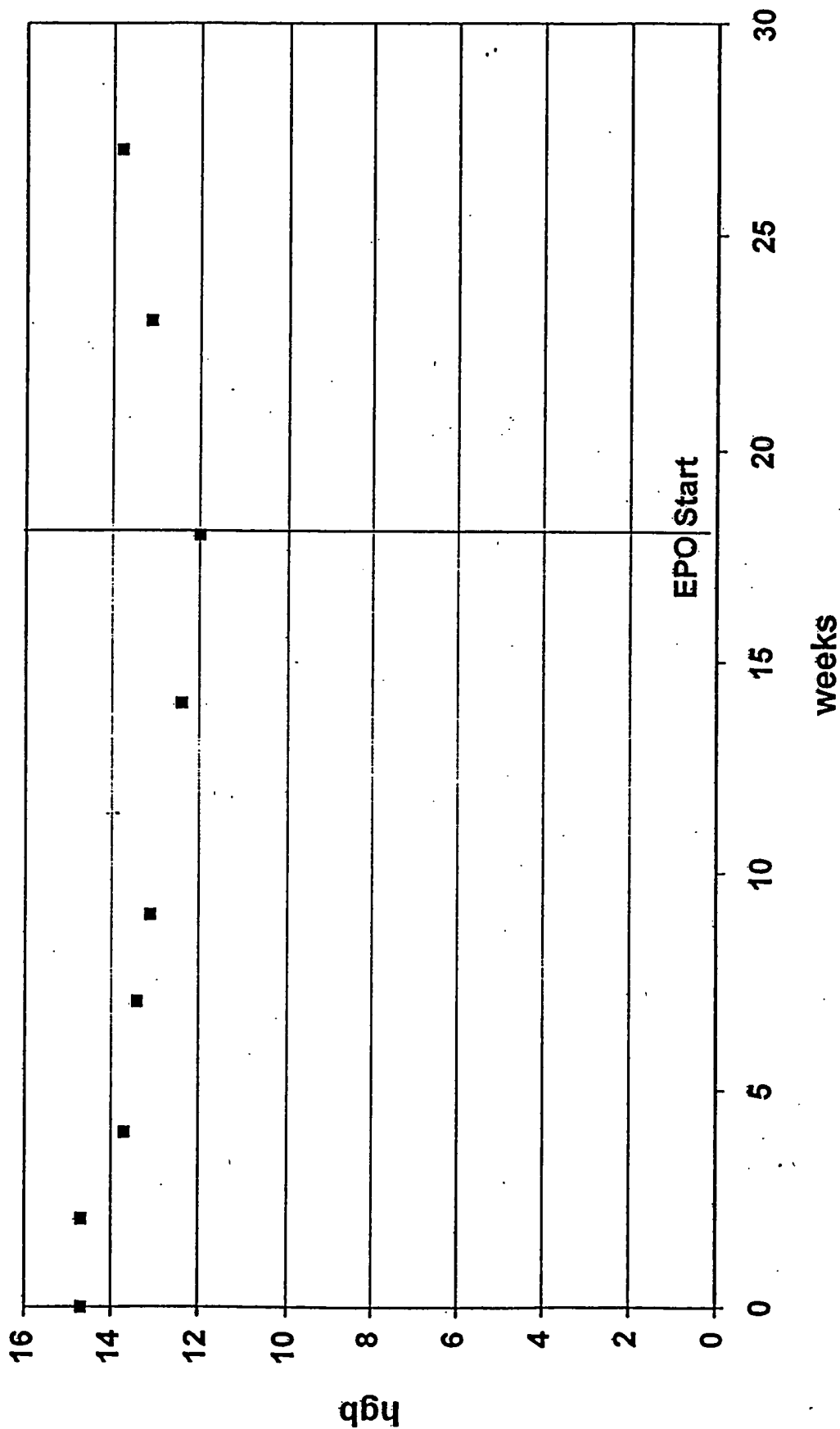
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Subject #16

FIGURE 2.12



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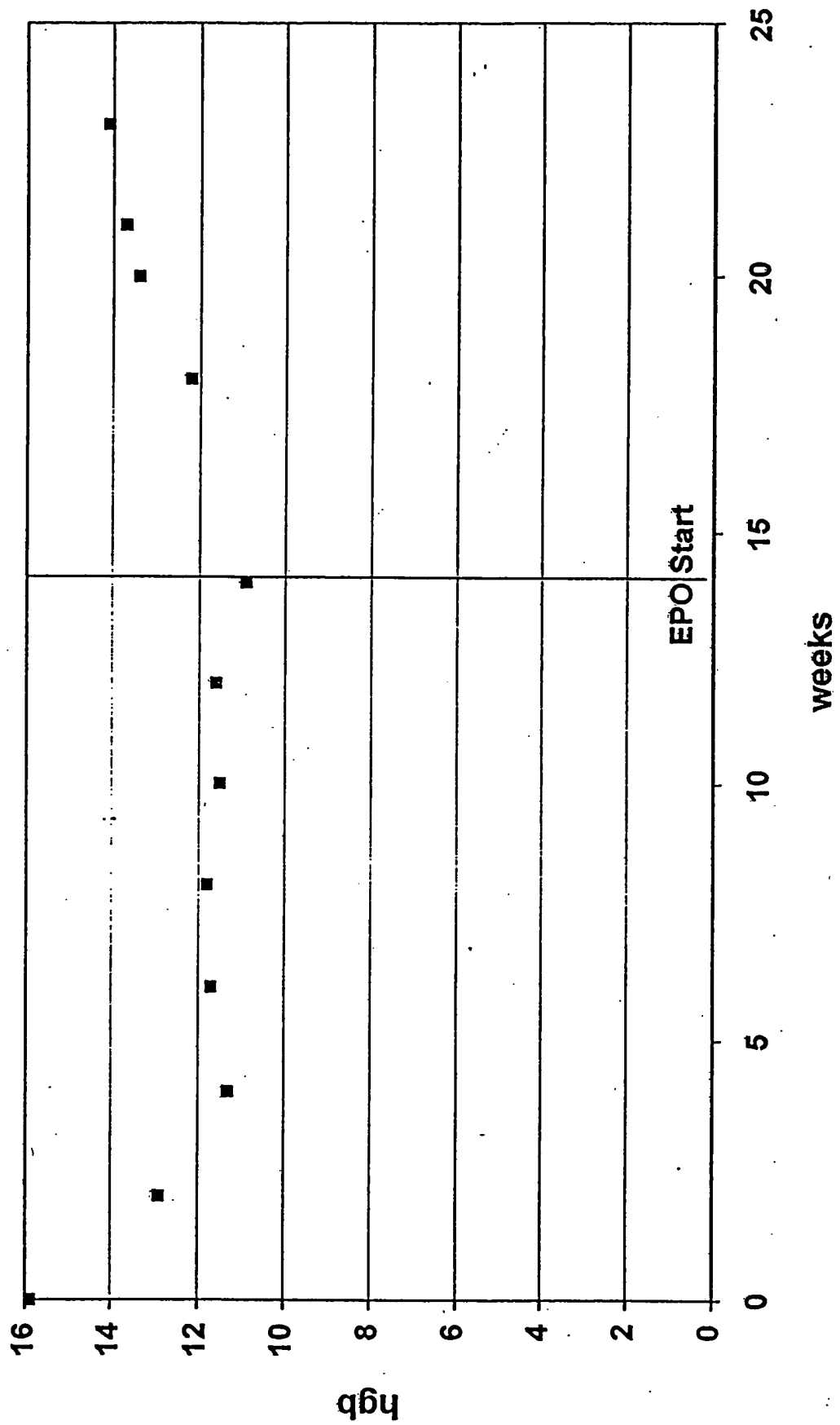


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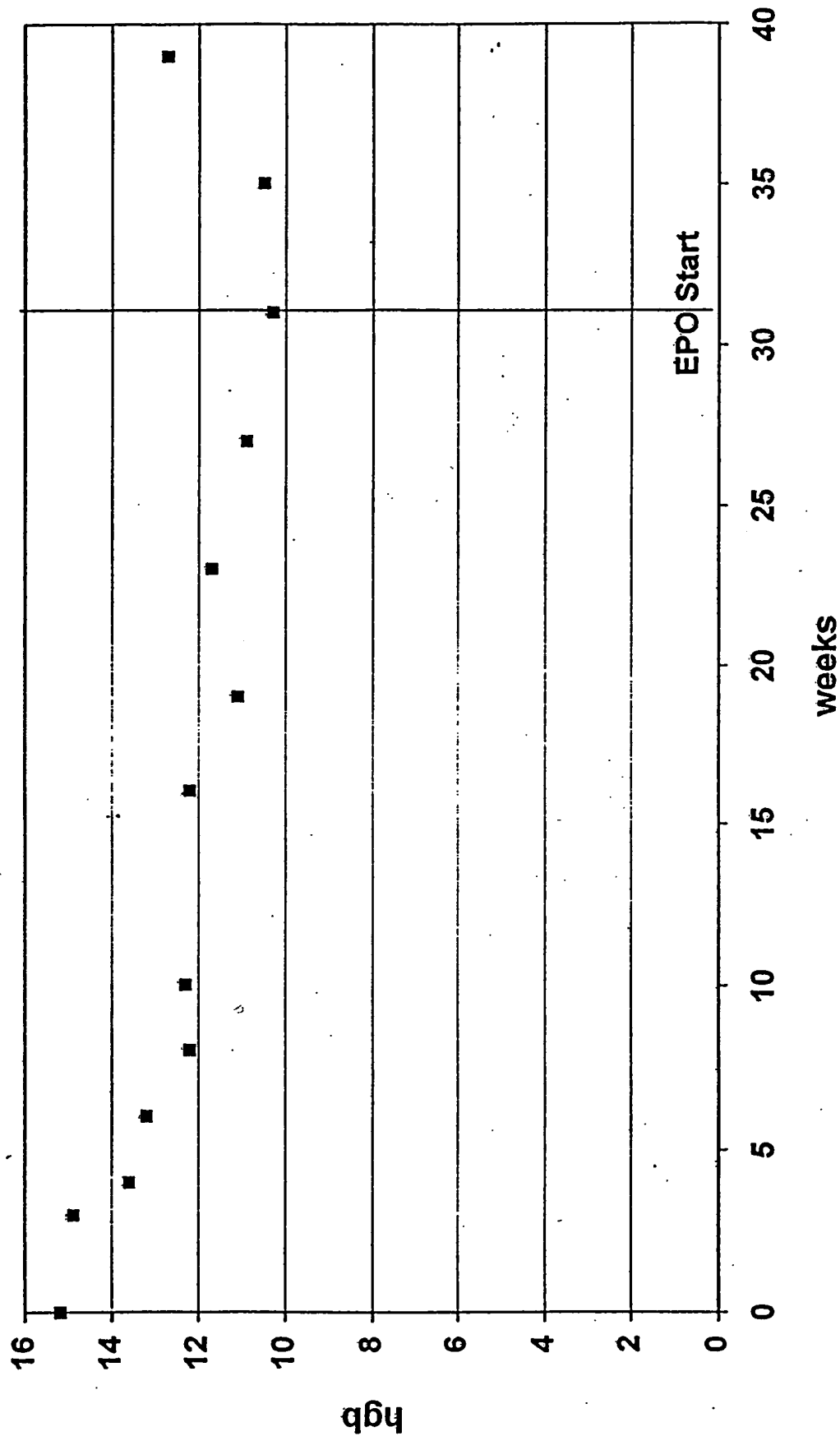
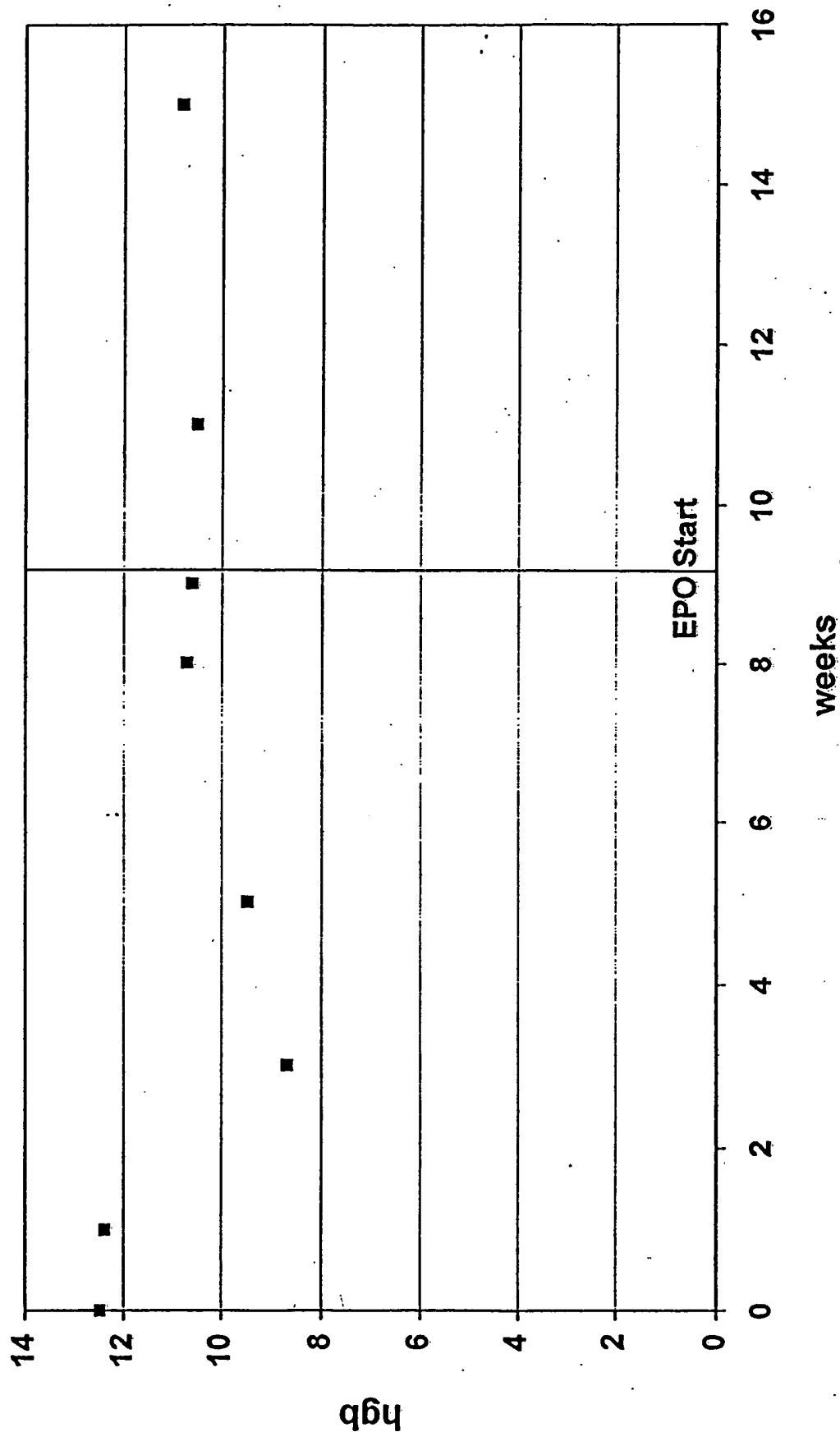


FIGURE 2.14

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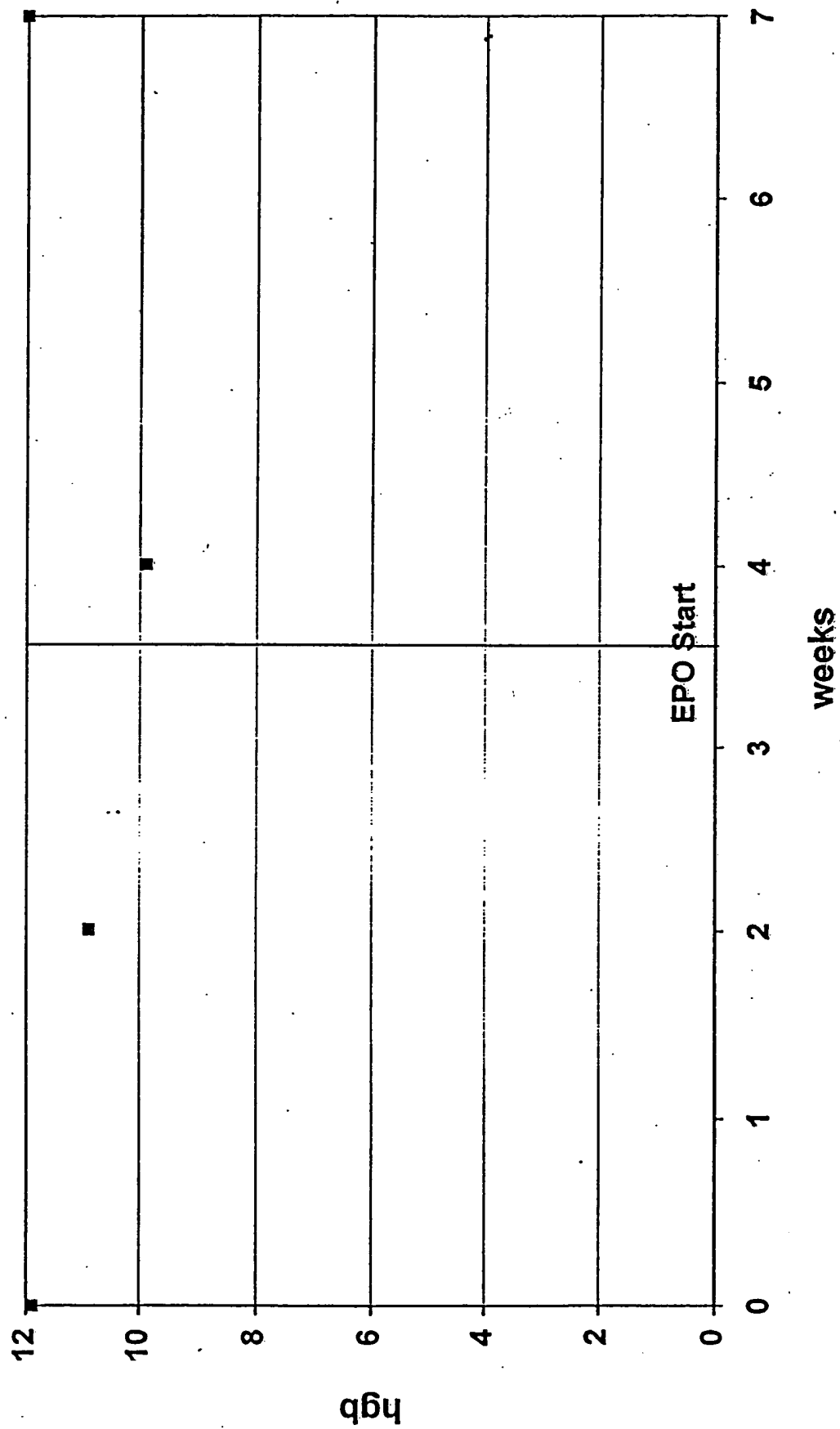
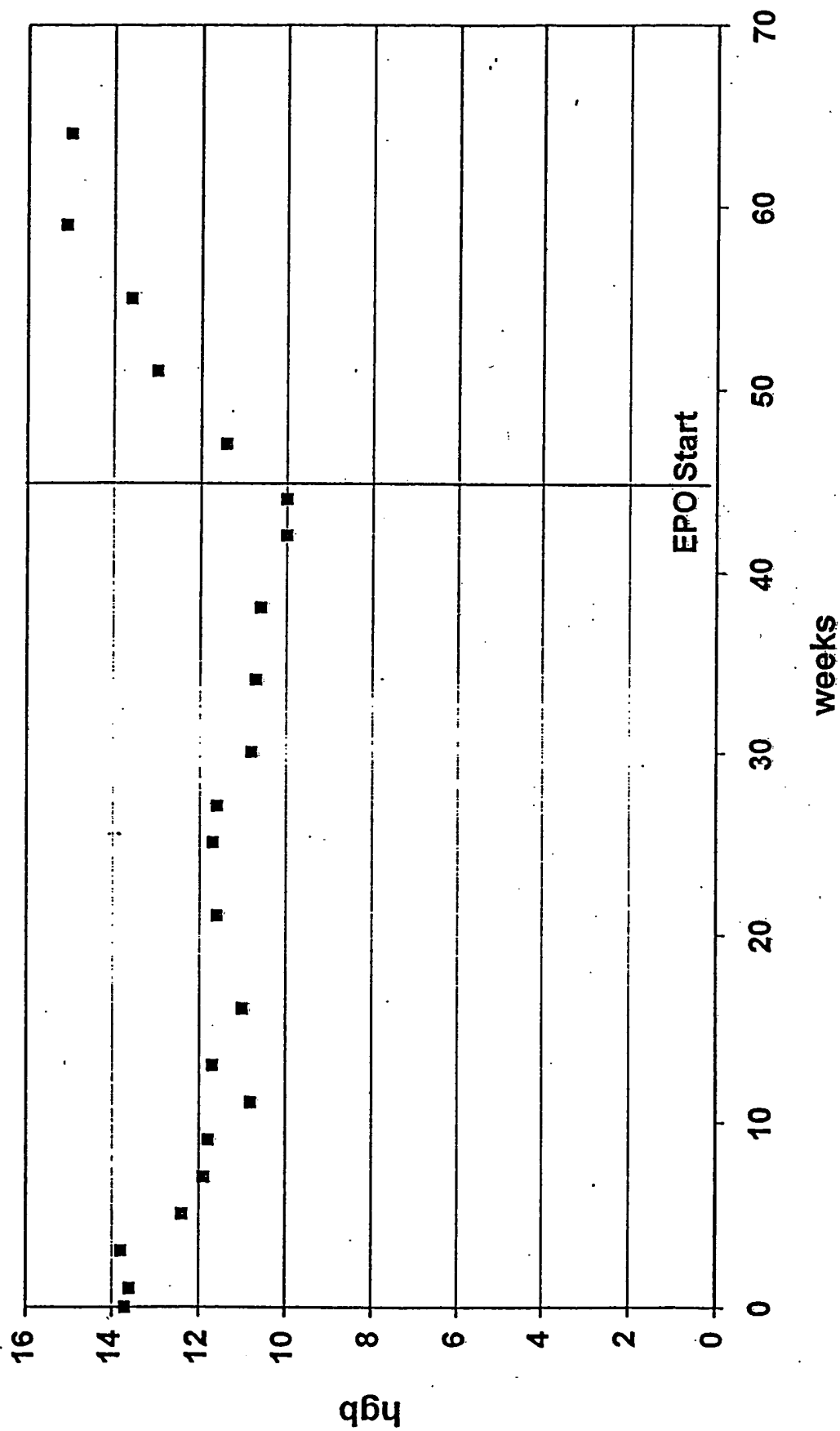


FIGURE 2.16

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Subject #22

FIGURE 2.17



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Subject #23

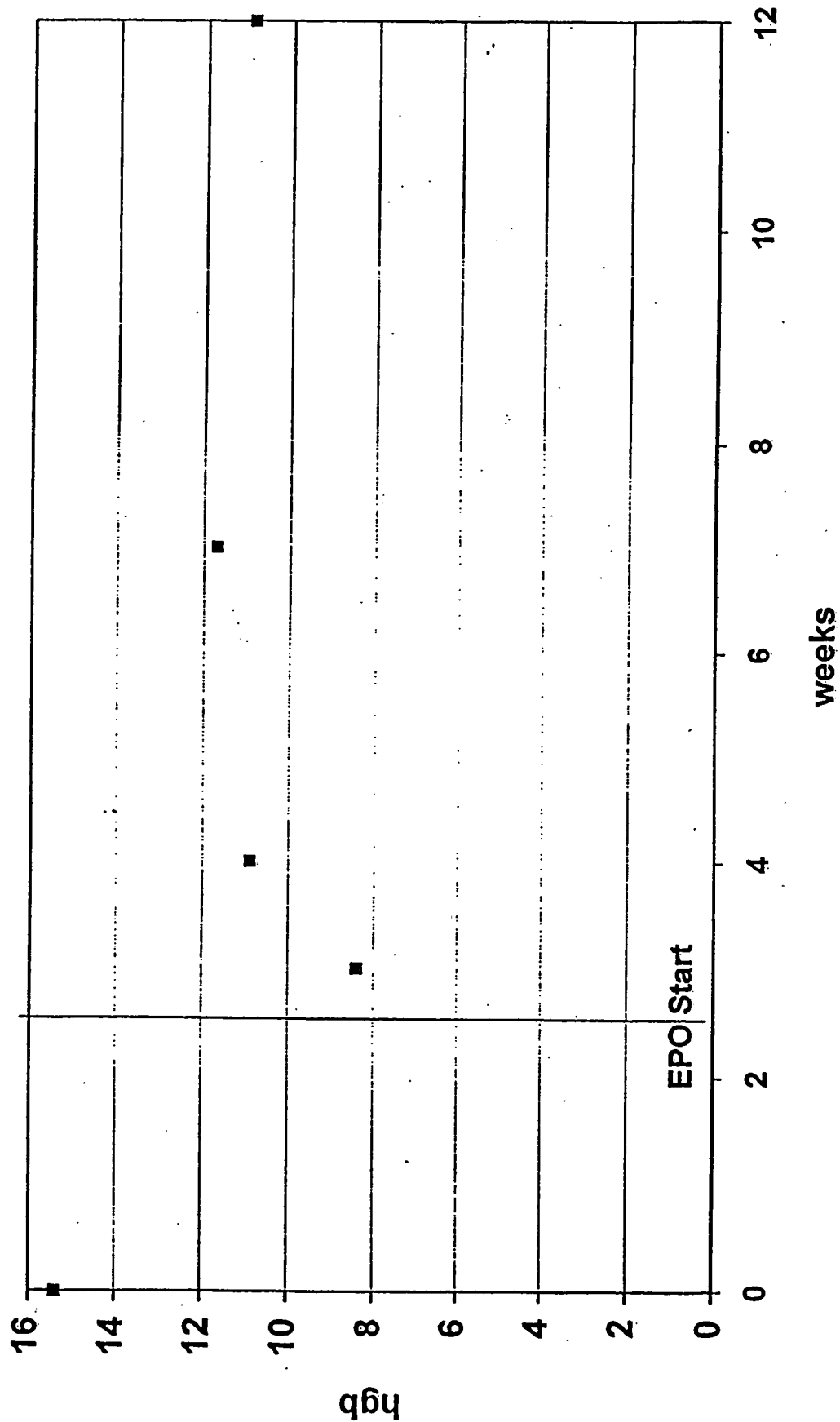


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